COVIX-19 Antigen Rapid Test Kit
Instructions For Use

PRODUCT NAME COVIX-19 Ag Rapid Test Kit

QUANTITY 25 Tests per Kit

REF COVIX-19-AG-RDT

For in vitro diagnostic use only. For use with nasopharyngeal swab specimens. For professional use only.

INTRODUCTION
The 2019 new coronavirus, or SARS-CoV-2, was discovered because of Wuhan Viral Pneumonia cases in 2019. COVID-19 is an infectious disease caused by SARS-CoV-2 with symptoms that commonly include fever, cough, shortness of breath, and in more severe cases, pneumonia and severe acute respiratory syndrome (SARS). SARS-CoV-2 belongs to the Betacoronavirus genus, which also includes Severe Acute Respiratory Syndrome coronavirus (SARS-CoV, 2003) and Middle East Respiratory Syndrome coronavirus (MERS-CoV, 2012). This professional-use lateral flow immunoassay test kit can be used as an aid in the diagnosis of individuals infected by SARS-CoV-2. The SARS-CoV-2 antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection.

INTENDED USE
COVIX-19 Ag Rapid Test is an in vitro rapid diagnostic test intended for the qualitative detection of the SARS-CoV-2 antigen in human nasopharyngeal swab specimens from patients suspected of Covid-19. The test is strictly for medical professional use only and is not intended for personal use. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulations. The test provides an initial screening result and should not be the sole basis for diagnosis, treatment or other patient management decisions, including infection control decisions.

TEST PRINCIPLE
The COVIX-19 Ag Rapid Test is a lateral flow immunochromatographic assay that utilizes a visual indication system consisting of a test line (T) and control line (C). Both lines are not visible in the result window before applying the specimen. The test contains a colloidal gold conjugate pad and a membrane strip that is pre-coated with antibodies specific to SARS-CoV-2 antigen on the test line and mouse monoclonal anti-Chicken IgY antibody on the control line. The specimen migrates along the membrane by capillary action. If SARS-CoV-2 antigen is present in the specimen, a visible colored band appears on the test lines (T) as antibody-antigen-antibody gold conjugate complex forms. If SARS-CoV-2 antigens are not present in the specimen then no colored test line will appear. The test cassette also contains a control line (C), which should appear regardless of the presence or absence of the test line. The control line confirms the test procedure was performed properly and must be visible or the test result is invalid.

MATERIALS REQUIRED

1. Stopwatch or Timer	3. Personal Protective Equipment as per local regulations
2. Tube Rack or Holder	4. Biohazardous waste container

MATERIALS PROVIDED

Number	Component		Contents
			25 tests/kit
1	Test Cassette	A nitrocellulose membrane coated with COVID-19 specific monoclonal antibodies and goat anti-rabbit IgY antibodies.	1 Test / Bag 25 Bags / Kit
2	Antigen Extraction R1	1% triton-100, 140mM NaCl, 1% sodium deoxycholate, 0.1% SDS, Tris-HCl buffer (pH7.4)	2 x 5mL Bottles
3	Antigen Extraction Tube		25 Pieces
4	Nasopharyngeal Swab		25 Pieces
5	Instructions For Use		1

STORAGE CONDITIONS AND SHELF LIFE
Store kits at 2℃ – 30℃ out of direct sunlight. Kit materials are stable until the expiry date printed on the packaging. Do not freeze kit. After the cassette bag is opened, the test cassette should be used within one hour.

CLINICAL TRIAL SUMMARY
The clinical performance of the COVIX-19 Ag Rapid Test for rapid detection of SARS-CoV-2 antigen was established in a study conducted at The Red Flag Hospital in Mudanjiang, China during the 2020 SARS-CoV-2 pandemic. Performance data was calculated from a study of individuals suspected of exposure to COVID-19 or who have presented with symptoms in the last 7 days. A total of 97 positive and 224 negative specimens were tested using the COVIX-19 Ag Rapid Test and results compared to a EUA RT-PCR reference method.

Method		PCR Test		Total Results
COVIX-19 Antigen Rapid Test Kit (Colloidal Gold)	Results	Positive	Negative	
	Positive	96	1	97
	Negative	5	219	224
Total Results		101	220	321

Relative Sensitivity	96/101	95.05% (88.93% - 97.87%)
Relative Specificity	219/220	99.55% (97.47% - 99.92%)
Accuracy	315/321	98.13% (95.98% - 99.14%)

*95% Confidence Interval.

TEST PROCEDURE

PREPARATION FOR TEST
1. Carefully read instructions for use of COVIX-19 Ag Rapid Test. Please also see the quick reference guide (with illustrations) before performing the test.
2. Check the expiry date on the back of the foil pouch. Do not use the kit if the expiry date has passed.

SPECIMEN COLLECTION
Specimen collection must be conducted by a trained healthcare worker.

PREPARE EXTRACTION TUBE
1. Place the included extraction tube in a tube holder.
2. Add 6 drops of Antigen Extraction R1 buffer to the extraction tube. Allow the solution to drip freely into the extractor tube without touching the edge of the tube. If the amount of buffer is excessive or insufficient, an improper test result may occur.

NOTE: The buffer bottle may be opened and resealed for each assay. The buffer cap should be firmly sealed between each use.

COLLECT PATIENT SPECIMEN
1. Let the patient's head relax naturally, and slowly insert a nasopharyngeal swab horizontally into the nasal cavity until resistance is met at the level of the turbinate.
2. Remove the swab from the package carefully. To avoid contamination, do not touch the head of the provided swab when opening the swab pouch.
3. Rotate the swab gently against the nasopharyngeal mucosa for 10 to 15 seconds.
4. Remove the swab carefully from the nostril.
5. Place the swab in the extraction tube containing the extraction buffer.
6. Swirl the swab for about 10 seconds and press the swab head against the tube wall to release antigen from the swab.
7. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
8. Press the nozzle cap tightly onto the tube.
9. Specimens should be tested as soon as possible after collection. If immediate testing is not possible specimens may be stored at room temperature (15-30℃) for up to 2 hours before analysis on the cassette.

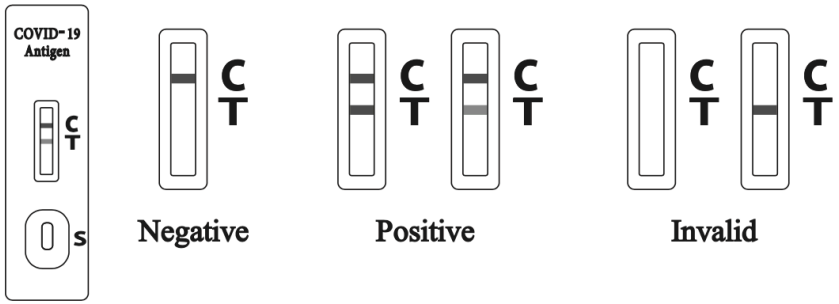
ANALYSIS OF SPECIMEN
1. Open the foil pouch and remove the test cassette and the desiccant package and check that is undamaged and dry. Discard the desiccant package and pouch. Use the test cassette within 2 hours of opening at room temperature (15-30℃).
2. Place the cassette on a level horizontal surface with the label facing up.
3. Apply 2 drops of extracted specimen into the specimen well, labelled S, on the test cassette. Start stopwatch or timer. Do not handle or move the test device until the test is complete and ready for reading.
4. Read results in 20 to 30 minutes. Do not read results after 30 minutes as these should be considered invalid. A positive result may appear before 20 minutes; however, negative results must be reported after 20 minutes.

Proprietary Innovation Labs Inc.
www.proinnolabs.com | hello@proinnolabs.com | +1 (647) 775-8985
345 Wilson Avenue, Suite 306, North York ON, M3H 5W1

COVIX-19 Antigen Rapid Test Kit
Instructions For Use

INTERPRETATION OF RESULTS

NEGATIVE RESULT	The C line is visible, and the T line is not visible. Negative results do not rule out a COVID-19 infection. Persons who test negative but continue to experience COVID-19 symptoms may still have SARS-CoV-2 infection and should consult with their healthcare provider.
POSITIVE RESULT	The C line and the T line are both visible, indicating a detection of COVID-19 antigens. Even if the T line is very faint or not uniform the test result should be interpreted as a positive. Follow up with a healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Positive results should be reported to local public health authorities where required
INVALID RESULT	If the C line is not visible, regardless of the T line being visible or not, the test is invalid.



LIMITATIONS OF TESTING METHOD

1. The test procedure and results must be performed and interpreted within strict accordance of this manual or invalid results may be obtained. All users must read the instructions prior to performing a test.
2. This test is only intended for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimens. Other sample types may lead to incorrect results.
3. This test is only intended to provide a qualitative detection and cannot indicate the concentration of SARS-CoV-2 antigens in the sample.
4. Immune response cannot be assessed with this test.
5. This test does not treat or cure COVID-19.
6. This test is a clinical auxiliary diagnostic tool and should not be used as a sole basis for diagnosis, treatment or patient management. Results must always be evaluated with other data available to the healthcare provider including patient's recent exposures, history and presence of clinical symptoms consistent with COVID-19.
7. Positive test results do not rule out co-infections with other pathogens.
8. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
9. Negative results may occur due to poor specimen collection, storage, or if the concentration of antigen is below the limit of detection of the test. Therefore, a negative result should be considered presumptive, and does not eliminate the possibility of a SARS-CoV-2 infection. Confirmation with a molecular assay may be required for patient management.

WARNINGS AND PRECAUTIONS

1. Do not re-use any component of the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not replace components in this kit with components from any other kit or lot.
4. Do not dilute the specimen prior to testing, otherwise you may get inaccurate results.
5. Do not use this test past its expiration date.
6. Do not open the cassette package before it is ready to be used for specimen analysis.
7. Allow all specimens and test components to come to room temperature before use if stored in a refrigerator. Do not open the pouch while components come to room temperature.
8. Testing should be performed in a laboratory or clinical setting.
9. All specimens and materials used should be handled in accordance with laboratory practices for infectious diseases established in your country or region.
10. Dispose of all specimens and test materials as biohazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Desiccant in the foil pouch is to absorb moisture and keep humidity from affecting products. Do not use the test cassette if it is moist.

INDEX OF RELEVANT AND APPLICABLE CE SYMBOLS:

IVD	For In-Vitro Diagnostic Use only.		Single Use Only
	Expiry Date		Refer To Instructions Before Use
	Please Refer to Instructions For Use		Manufacturer Name
2°C 30°C	Storage and Temperature Range	LOT	LOT / Batch Code
EC REP	Authorized European Representative		Keep Dry
	Avoid Prolonged Sun Exposure		Do Not Use if Packaging is Damaged
	Date of Manufacture		Biohazardous Material Risk
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Xiamen AmonMed Biotechnology Co., Ltd.
Address:120 Xinyuan Road, Haicang District, Xiamen, China.

EC REP

SUNGO Europe B.V.
Address: Olympisch Stadion 24,1076 DE Amsterdam, Netherlands
E-mail: ec.rep@sungogroup.com
Tel: +31(0)202111106

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. External control standards are not supplied with this test. However, it is recommended that positive and negative external controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

DISTRIBUTED BY:

Proprietary Innovation Labs Inc.
345 Wilson Avenue, Suite 306, North York ON, M3H 5W1
hello@proinnolabs.com
Please contact us for any complaints/inquiries/suggestions via email (hello@proinnolabs.com), phone (647-775-8985) or website (www.proinnolabs.com).

CE
IVD

APPROVAL AND REVISION DATE OF INSTRUCTIONS

Approval. 2020.09.16
Rev 1. 2020.10.13
Rev 2. 2020.11.23
Date of Issue: 2020.11.05
Version 2.1.R